

**REMARKS**

Reconsideration and withdrawal of the rejections of this application are respectfully requested in view of the remarks and amendments herewith.

Claims 1 and 3-11 are pending in the subject application. Applicants have amended claims 1 and 3-11 and cancelled claims 2, 12 and 13 of the subject application without prejudice. Applicant reserves the right to pursue the subject matter of the canceled claims in one or more divisional applications.

As a preliminary matter, Applicants thank the Examiner for noting that claim 3 would be allowable if rewritten in independent form.

No new matter has been added.

**Election Restriction**

The Examiner has acknowledged Applicant's election of Group I claims. Applicants have amended the claims, without prejudice, to remove non-elected subject matter.

Applicants respectfully request rejoinder of claim 10 as the compounds recited in claim 10 falls within the elected group, imidazo[1,2-a]pyridines (compounds of formula I wherein Y is carbon).

**Information Disclosure Statement**

The Examiner is thanked for acknowledging the IDS filed on September 13, 2006.

**Objections to the Specification**

The title is objected as allegedly not descriptive. The title has been amended to overcome the objection. The Examiner is thanked for suggesting an alternate title. No new matter has been added.

Accordingly, withdrawal of this objection is respectfully requested.

**Objections to the Claims**

Claims 1, 4 and 9 have been amended to correct informalities. Even though it is believed the term "heterocyclo" is well known in the art and is specifically supported on page 18, line 28 through page 19, line 22, as being synonyms with heterocyclyl, Applicants have amended the claims as suggested by the Examiner to facilitate prosecution. In addition, claims 5-8 and 11 have been amended to correct dependencies.

Accordingly, withdrawal of these objections is respectfully requested.

**I. REJECTION OF CLAIMS 1 AND 4 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

Claims 1 and 4 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/use the invention. Specifically, the Examiner alleges that "while being enabling for compounds of Formula 1, wherein  $X^1=NH$  and  $O$ ;  $X^2=$ absent;  $R^3= (C_1-C_6)$ alkyl, heteroaryl,  $C(O)NRaRb$ ,  $C(O)Ra$  does not reasonably provide enablement for compounds of Formula 1, wherein  $X^1=CH_2$ ;  $X^2=NH, O, (CH_2)_x$ cyclopropyl with various points of attachment, or a tether as illustrated in claim 1;  $R^3=(C_3-C_6)$ cycloalkyl, aryl, heterocyclo,  $CO_2Ra$ ,  $C(O)C(O)NRaRb$ ,  $NO_2$ ,  $SO_2Ra$ ,  $SO_2NRaRb$ ,  $C(Rc)=NORa$ ,  $C(Rc)=NRa$ ,  $C=N-NRaRb$ ,  $C=N-NC(O)Rc$ ." (*Office Action*, at 4). The rejection is traversed.

Applicants now address each of the Wands factors which support a finding that the pending claims are fully enabled.

**The Nature of the Invention**

The nature of the invention is a compound of formula I or a pharmaceutically acceptable salt thereof. Applicants believe the invention is fully enabled by the specification for making and using the claimed compounds.

**The Breadth of the Claims**

The Examiner further alleges that the invention is "highly substituted imidazo [1,2-a] pyrimidines". Applicants don't disagree that the scope of the claims includes many compounds of formula I. However, Applicants disclosure more than sufficiently delineates the compounds of formula I. One of ordinary skill in the art certainly has no difficulty in reading each of the discrete elements of claim I. One skilled in the art could readily determine any one of the claimed embodiments of the present invention. Section 112 requires only that the scope of protection sought in a claim bear a "reasonable correlation" to the scope of enablement provided by the specification. *In re Wright*, 999 F.2d 1557, 1561 (Fed.Cir.1993). The record is clear and thus the public will have notice as to Applicants' scope of protection when the patent issues. The guidance provided in the description in the specification is sufficient to enable one of skill in the art to practice the invention over the full scope of the claims.

**The State of the Prior Art, Predictability, Guidance and Working Examples**

Applicants respectfully submit that the working examples and guidance provided in the description in the specification is sufficient to enable one of skill in the art to practice the invention over the full scope of the claims. Applicants respectfully direct the Examiner's attention to the detailed synthetic schemes that have been provided. Applicants have provided detailed synthetic schemes (Schemes 1 through 7) on pages 22-27 that teach one of ordinary skill in the art how to make the claimed compounds of the present invention. Moreover, Applicants have provided a detailed written description on pages 22-27 of the reaction steps employed in the aforementioned synthetic schemes. The specification also sets forth in detail

over 50 representative examples of compounds of the claimed invention that were prepared using the disclosed synthetic schemes. All the descriptions in the specification that are referred to above are written in clear and concise language using terms that are familiar to those skilled in the art.

Applicants respectfully submit that they have taught those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. The law does not require Applicants to disclose an example of every claimed compound yet the specification provides a large number of working examples. Further, preparation of additional compounds is a matter of routine experimentation given that the high level of skill and knowledge in the art (which the Office admits). Applicants' disclosure coupled with the high level of skill in the art is sufficient to enable one of ordinary skill in the art to practice the full scope of the claimed invention.

Moreover, the specification sets forth in detail, on page 2, that the compounds of the present application exhibit antibacterial activity. Further, on pages 84-89 (Example 52) the specification sets forth *in vitro* tests which can be followed to assess the activity of any compound falling within the scope of the present application. The foregoing information is sufficient to enable one skilled in the art now to make and use the instant invention and thus complies with the requirements of 35 U.S.C. §112, first paragraph.

On page 6 of the Action, the Office alleges that "Applicant shows a general synthesis of compounds of Formula 1, under Preparation on pages 23-27 of the Specification, but does not show the starting material used to make the variety of compounds claimed." Applicants respectfully submit that the specification contains support sufficient to enable those skilled in the art to practice the inventions of each of the claims. Specifically, Applicants' specification adequately discloses to one skilled in the relevant art how to make the claimed invention, including the starting materials, without undue experimentation.

The specification discloses to one of ordinary skill in the art how to make the compounds of formula I wherein  $X_1 = CH_2$ . Specifically, Schemes 5, 6, 7 and Examples 6, 7, 23, 27, and 45 illustrate the reaction of an "-NH<sub>2</sub>" group at the 2 position of the subject imidazopyridine template with an electrophile. More specifically, in example 27, the electrophile is an acid chloride. One skilled in the art would immediately recognize that a compound of formula I wherein  $X_1 = CH_2$  would be prepared by reaction of the desired 2-NH<sub>2</sub> intermediate with any of the many widely available acid chlorides of the formula " $ClC(=O)CH_2R$ " according to the method disclosed in example 27.

The specification discloses to one of ordinary skill in the art how to make the compounds of formula I wherein  $X_2 = NH$ , O. Specifically, Schemes 5 and 6 outline two stepwise methods for the preparation of compounds with  $X_2 = O$ . The schemes reference published precedent for the described reactions and proceed from a known starting material, 4,6-dichloro-2-aminopyridine, referenced in Scheme 5 to WO 2001087854 A1. In both methods, one skilled

in the art would recognize the application of a standard method known commonly as "nucleophilic aromatic substitution" for the incorporation of the  $X_2=O$  atom and its associated  $R_3$  group. One of ordinary skill in the art would be aware that substituting a primary amine for the described primary alcohol in Schemes 5 and 6 would result in the synthesis of analogous compounds having  $X_2=NH$  rather than O. One of ordinary skill in the art may opt, instead, to utilize either intermediate 2 or 5 in Example 23 wherein the requisite  $X_2=NH$  group is present, and introduce  $R_3$  using commonplace alkylation methods that would be immediately familiar.

The specification discloses to one of ordinary skill in the art how to make the compounds of formula I wherein  $X_2=(CH_2)_x$ , cyclopropyl with various points of attachment, or a tether. Specifically, Scheme 5 illustrates, with reference to published literature, the synthesis of an intermediate imidazopyridine with  $R_3=Cl$  and  $X_2$  absent. From this intermediate, one skilled in the art would prepare, without undue experimentation, products of Suzuki, Stille, Negishi, Heck, Kumada, or other carbon-carbon bond forming transition metal catalyzed coupling reactions well known in the art. Such a coupling reaction is exemplified in Example 23 (Step 8). The variety of  $X_2=(CH_2)_x$  may be prepared in this manner. The skilled artisan may opt to utilize, instead, any of intermediates 4,5,6,7,8,9,10,11, or 12 of Example 7 wherein the required  $X_2=CH_2$  group is already in place. Functionalization of said intermediates for the purpose of accessing the breadth of claimed matter derived from  $X_2=(CH_2)_x$  would be accomplished utilizing  $SN_2$  alkylation chemistry that is commonplace to one skilled in the art.

The specification discloses to one of ordinary skill in the art how to make the compounds of formula I wherein  $R_3=(C_3-C_6)$ cycloalkyl, aryl, heterocyclyl,  $C(O)C(O)NRaRb$ ,  $NO_2$ ,  $SO_2Ra$ ,  $SO_2NRaRb$ . One skilled in the art would immediately recognize how to incorporate these functional groups utilizing the methods and intermediates described above, wherein, the desired functional group is present in the starting material utilized as above.

The specification discloses to one of ordinary skill in the art how to make the compounds of formula I wherein  $R_3=C(Rc)=NORa$ ,  $C(Rc)=NRa$ ,  $C=N-NRaRb$ ,  $C=N-NC(O)Rc$  – These functional groups are all formed by the condensation of a primary amine with a carbonyl functional group, a commonplace reaction that has been practiced for more than 100 years. One of ordinary skill in the art would immediately recognize the utility of intermediate 13 in Example 7, bearing a carbonyl at the requisite  $R_3$  ( $X_2=absent$ ) position for the synthesis such functional groups at  $R_3$  without undue experimentation.

Accordingly, Applicants' disclosure (guidance and working examples) coupled with the high level of skill in the art is sufficient to enable one of skill in the art to practice the invention over the full scope of the claims.

**Quantity of Experimentation**

The Office concludes that undue experimentation would be required to practice the invention because "[d]ue to the level of unpredictability in the art, the very limited guidance provide, and the lack of working examples. . .". *Office Action* at 7. The courts have established that additional experimentation can be performed while meeting the requirements of 35 U.S.C. § 112. "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed..." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *Ex Parte Jackson*, 217 USPQ 804 (Bd. App. 1982)). Thus, the fact that additional experimentation may be required is not sufficient to suggest that the claims are not enabled. Applicants have provided adequate description in the specification to enable one of skill in the art to practice the claimed invention with merely routine experimentation.

Based on all of the Wands factors and consideration of the evidence as a whole, it is respectfully submitted that the patent application includes a description of the claimed invention in compliance with § 112, such that the rejection, upon reconsideration, should be withdrawn. Accordingly, reconsideration and withdrawal of the rejection to claims 1 and 4 are respectfully requested.

**CONCLUSION**

In view of the remarks and amendments, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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